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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,013	04/04/2006	Rudolf Fahrig	P28506	8056
7055 7590 07/02/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 07/02/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/550,013

Applicant(s)

FAHRIG ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/07/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-26 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “protective form” in claims 8-10 render the claims indefinite. More specifically, it is unclear what constitute a protective form and what is being protected from or against.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1623

Claims 8-12, 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahrigr et al. (WO 96/23506, Abstract Only).

In claim 1, applicant claims a method of increasing apoptotic effect of cytostatics after chemotherapy comprising administering a 5-substituted nucleoside comprising (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU), a protected form, salt, prodrug or mixture thereof, the administering being without administration of a cytostatic, during a recovery phase after a cytostatic chemotherapy cycle. Claims 9 is drawn to said method wherein the administration includes cytostatic and a 5-substituted nucleoside comprising BVDU, a protected form, salt prodrug, or mixture thereof. Claim 10-12, 16, 17 are drawn to said method involving the administration of specific amounts of cytostatic and BVDU, specific recovery phase and chemotherapy cycle, and specific concentration of 5-substituted nucleoside in the blood and specific cytostatics.

Fahrigr et al. disclose that 5'-substituted nucleosides in combination with at least one cytostatic can be used in the production of a medicament to prevent or reduce the build-up of resistance in cytostatic treatment and a medicament containing BVDU and/or its metabolites (see abstract). It should be noted that the apoptotic effect encompasses the cytostatic treatment disclosed by Fahrigr et al.

The difference between applicant's claimed method and the method suggested by Fahrigr et al. is that Fahrigr et al. do not disclose administering said BVDU during the recovery phase after a cytostatic chemotherapy cycle. However, Fahrigr et al. suggest that BVDU can cause the apoptotic effect of the cytostatic to be more effective (i.e., increased) due to the build-up of resistance in cytostatic treatment.

Art Unit: 1623

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Fahrigh et al., to increase apoptotic effect of cytostatics after chemotherapy comprising administering said BVDU, during a recovery phase after a cytostatic chemotherapy cycle based on factors such as the condition (especially after chemotherapy cycle) and the type of individual treated, since Fahrigh et al. disclose that BVDU and/or its metabolites can reduce the build-up of resistance in cytostatic treatment.

One having ordinary skill in the art would have been motivated, in view of Fahrigh et al. to increase apoptotic effect of cytostatics after chemotherapy comprising administering said BVDU, during a recovery phase after a cytostatic chemotherapy cycle based on factors such as the condition (especially after chemotherapy cycle) and the type of individual treated, since Fahrigh et al. disclose that BVDU and/or its metabolites can reduce the build-up of resistance in cytostatic treatment. It should be note that the use of specific ratios of drugs, agents or cytostatics and frequency of administration depends on factors such as the type and severity of the condition treated and the kind of subject treated.

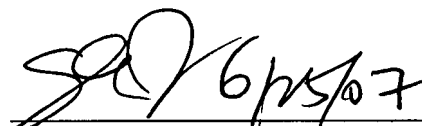
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

A handwritten signature in black ink, appearing to read 'SAJ 6/25/07', is written over a horizontal line.

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 24, 2007.